September 15, 2006

Update for Health Screening Services (9 AAC 14, Article 7)

The Department has submitted a Notice of Proposed Rulemaking for the rules in Title 9, Chapter 14, Article 7. The proposed rules simplify the requirements for health screening laboratory services and make them consistent with federal CLIA requirements. The intent is that health screening laboratory tests be performed by a facility that has one of the four types of CLIA certificates. The four types of CLIA certificates are:

- Certificate of compliance,
- Certificate of accreditation,
- Certificate for provider-performed microscopy (PPM) procedures, and
- Certificate of waiver.

To be consistent with CLIA regulations, exemptions are made for:

- Laboratories performing forensic testing or research,
- Urine tests performed for drugs of abuse for employment purposes,
- Tests performed under the jurisdiction of the Department of Veteran's Affairs or a component of the Department of Defense, and
- Tests performed using available over-the-counter test kits on specimens derived from the individual performing the test (such as self-testing by a diabetic for blood glucose monitoring, but including situations where a parent or other family member might perform a test on a child's specimen; or a home heath aide might assist someone in performing a self-test).

The Notice of Proposed Rulemaking was published in the *Arizona Administrative Register* on September 15, 2006. The Oral Proceeding for this rulemaking is scheduled for October 16, 2006, at 1 p.m., at the Arizona State Laboratory, 250 N. 17th Avenue, Phoenix, Arizona 85007.

Stakeholders are asked to send any comments to Ruthann Smejkal, Rules Analyst for the Department, by e-mail at smejkar@azdhs.gov, by phone at 602-364-3959, or by fax at 602-364-1150.